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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,356	10/01/2003	Johann Kindlein	3560-0133P	3817

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

LUSTUSKY, SARA

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,356	KINDLEIN ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-12, 14-18 is/are rejected.
- 7) ☒ Claim(s) 9 and 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/01/03</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.
2. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.
3. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.
4. The abstract of the disclosure is objected to because it exceeds the 150-word limit.

Correction is required. See MPEP § 608.01(b).

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

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- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and

problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the

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World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claims 12 and 16-18** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claim 12, the limitation "more in particular" at line 2 renders the claim indefinite because it is unclear whether the limitations preceding the phrase are part of the claimed invention.

9. Claim 16 recites the limitation "the open proximal end of said tube-shaped element" in line 1. It is not definite that the open end of the tube-shaped element is the proximal end according to the claim language of claim 1, therefore there is insufficient antecedent basis for this limitation in the claim.

10. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language. These claims are omnibus type claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claim 17** is rejected under 35 U.S.C. 102(b) as being anticipated by Bradshaw et al. (US 5092834 A).

13. Bradshaw et al. teaches a seed loading apparatus provided with an implanting device (as described in claim 1).

14. **Claim 18** is rejected under 35 U.S.C. 102(b) as being anticipated by Tucker et al. (US 5976067 A).

15. Tucker et al. teaches a row of radioactive seeds (24, 28, 32, 36) and non-radioactive spacers (26, 30, 34) in a desired configuration (as seen in Figures 4 and 5), wherein said seeds and spacers are accommodated in a tube-shaped element (12) (as described in lines 28-31 of column 5 and in lines 23-32 of column 6).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. **Claims 1-3, 5-8, 11-12, 14 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5928130 A) in view of Tucker et al. (US 5976067 A).

18. Schmidt teaches a device (10) for implanting at least one row of radioactive seeds (22) and non-radioactive spacers (24) in a desired configuration to a desired location in an animal body, said device (10) comprising: at least one elongated hollow needle (12) with an open end (14) to be inserted toward said desired location and a proximal end (16) to be connected to a seed loading apparatus; at least one pushing element (26); and at least one tube-shaped sleeve member (18) (as seen in Figures 1-3), wherein the at least one tube-shaped sleeve member is transparent (as described in lines 1-8 of column 3); wherein said pushing element (26) is constructed as a rigid pushing rod (as described in lines 59-62 of column 2); wherein said tube-shaped sleeve member (18) is provided at its proximal end with a stopper element (20) constructed as a disc shaped end plate (as described in lines 50-53 of column 2); wherein the outer dimensions of the tube-shaped sleeve member (18) and the row of seeds and spacers are equal or slightly smaller than the inner dimensions of said hollow needle and wherein the inner dimensions of the tube-shaped sleeve member are equal or slightly larger than the outer dimensions of the row of seeds and spacers (as described in lines 47-58 of column 2), wherein the row of radioactive seeds and non-radioactive spacers are inserted through said needle prior to insertion towards said desired location in the body. While Schmidt teaches the implantation of a row of seeds and spacers, Schmidt is silent as to the type.

19. Tucker et al. teaches an implantable row of seeds (24, 28, 32, 36) and spacers (26, 30, 34) (as seen in Figure 4), wherein the row delivers radioactive and thermal treatment to a desired location in an animal body (as described in lines 33-38 of column 2 and in lines 28-31 of column

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5), wherein the row of seeds comprises a tube-shaped element (12) with two ends (21, 23) that are open for a portion of the length and closed for the remaining portion of the length, wherein the open portions are collapsible, wherein the tube-shaped element (12) has a circular cross section (as described in lines 28-31 of column 5 and in lines 23-32 of column 6).

20. It would have been obvious to one of ordinary skill in the art at the time of the invention to implant a row of seeds similar to those of Tucker et al. with a device similar to that of Schmidt in order to enable a physician to determine quickly and easily the number of seeds and spacers that have been implanted during a procedure.

21. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Schmidt (US 5928130 A) and Tucker et al. (US 5976067 A) as applied to claim 1 above, in view of Bradshaw et al. (US 5092834 A).

22. The combination of Schmidt and Tucker et al. teaches a device for implanting radioactive seeds and non-radioactive spacers comprising at least one hollow needle, a pushing element, one tube-shaped element and at least one tube-shaped sleeve member, wherein said pushing element is a push-rod, as described above. While this combination teaches that the seeds and spacers require a pushing element to force them out of the needle and into the tissue of the patient, a drive wire is not taught as an alternative pushing element.

23. Bradshaw et al. teaches a seed loading apparatus comprising a drive wire for loading an implanting device comprising a hollow needle with radioactive seeds and for pushing said seeds into the tissue of a patient (as described in claim 1).

24. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a drive wire similar to that taught by Bradshaw et al. to implant the radioactive seeds and non-radioactive spacers of Schmidt and Tucker et al. because one of ordinary skill in the art would have expected the combination of Schmidt and Tucker et al. and applicant's invention, to perform equally well with either a push rod as taught by the combination of Schmidt and Tucker et al. or the claimed drive wire of the seed loading apparatus because both would perform the same function of pushing the radioactive seeds and non-radioactive spacers out of the needle and into the tissue of the patient.

25. **Claims 10 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Schmidt (US 5928130 A) and Tucker et al. (US 5976067 A) as applied to claim 1 above, in view of Lowery et al. (US 2003/0109769 A1).

26. The combination of Schmidt and Tucker et al. teaches a device for implanting radioactive seeds and non-radioactive spacers comprising at least one hollow needle, a pushing element, one tube-shaped element and at least one tube-shaped sleeve member. While this combination teaches the implantation of a row of seeds and spacers, it does not teach that the tube-shaped element is bio-absorbable.

27. Lowery et al. teaches an implantable row of seeds and spacers (as described in paragraph [0013] and [0018]), wherein the row is encased in a bio-absorbable tube-shaped element (as seen in Figures 39 and 45), wherein the tube-shaped element comprises a flexible material capable of exerting an inwardly directed force on the row of seeds and spacers in order to keep the row from migrating away from the implantation site (as described in paragraphs [0017] and [0149]).

28. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the tube-shaped element in a device similar to that taught by the combination of Schmidt and Tucker et al. from a bio-absorbable material similar to that of the tube-shaped element of Lowery et al. in order to hold the treatment, such as radioactive seeds and non-radioactive spacers, in a desired configuration within the body until the treatment has been delivered and to eliminate the permanence of the tube-shaped holding device within the patient in order to decrease the irritation to the body tissue that usually accompanies an implanted device.

Allowable Subject Matter

29. **Claims 9 and 13** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

30. Regarding claim 13, none of the prior art of record teaches or fairly suggests a device for implanting a row of radioactive seeds and non-radioactive spacers comprising a needle, a pushing element, a tube-shaped element and a tube-shaped sleeve, wherein prior to the insertion through the hollow needle the tube-shaped element has an oval-shaped cross section and a circular cross section when inserted in the hollow needle.

31. Regarding claim 9, none of the prior art of record teaches or fairly suggests a device for implanting a row of radioactive seeds and non-radioactive spacers comprising a needle, a pushing element, a tube-shaped element and a tube-shaped sleeve, wherein the length of the tube-shaped element is greater than or equal to that of the row of seeds and spacers and wherein

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the length of the tube-shaped sleeve is less than or equal to the difference in length between the needle and the tube-shaped element.

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Terwilliger et al. (US 2003/0092958 A1) teaches a type of seed having an open end and a protruding end.

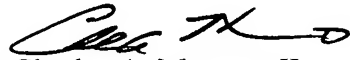
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


S.L.


Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735